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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,027	07/16/2003	Evan C. Unger	5030-0003.01	1650

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,027	UNGER, EVAN C.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-20 and 23-45* is/are pending in the application.

4a) Of the above claim(s) *11,12,16-18,26-27 and 29-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-10,13-15,19-20,23-25,28 and 39-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 10/27/2006 is acknowledged and applicants election with traverse of the species election. The traversal is on the ground(s) that Groups I and II are not directed to distinctly different inventions because all of the claims are drawn to solid porous matrices or to methods fabricating the same, and the differences between these groups will not impose an undue burden on the examiner. This is not found persuasive because as stated in the last office action Groups I and II are related as process of making and product made and a search for the product and the process of making would not necessarily result in the same field of search, especially since the product as claimed can be made by another and materially different process such as pore formation by dissolution of pore formers embedded in the matrix for example. Applicants then state that the election of species was not proper because the species are sufficiently few or so closely related that a search and examination can be made without serious burden on the examiner. The examiner disagrees, numerous therapeutics, surfactants are claimed and a search for all of the disclosed species in the Markush groups above would be burdensome as a search for all the species claimed would not necessarily result in the same field of search. The examiner upon searching for the therapeutic compositions did find the arguments from applicants that the two physical states would not be burdensome to search, therefore the examiner will search for a therapeutic composition that is in a dried state and rehydrated with a liquid (see 112 rejection below).

The requirement is still deemed proper and is therefore made FINAL.

The claims which are searchable with the above restriction and species elected are claims 1-4,6-10,13-15,19-20,23-25,28 and 39-45.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how a therapeutic composition can have a solid porous network if the composition is in a liquid state, this seems to be a flaw in how the claims were worded. The examiner upon review of the specification and claim 43 believes the solid porous matrix is rehydrated with a liquid solution and to expedite the examining process will search the claims with the above limitation (same as claim 43).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,6-9,13-15,19-20,23-25 and 39-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Unger et al. (US 5,469,854).

Unger teaches a method of preparing gas filled liposomes, which are disclosed as useful in ultrasonic imaging and therapeutic drug delivery. See abstract. The liposomes can be stored in the dry state and then resuspended latter in a liquid medium, the drying could be achieved by lyphilization. See col 3 lin 33-50, col 6 lin 8-24 and examples. The therapeutic compositions in Unger comprise other additional ingredients such as emulsifiers, suspending and or/viscosity modifiers including glycerol, polyethylene oxide, polypropylene glycol, polyvinyl alcohol and propylene glycol. See col 13 lin 25-54, col 15 lin 31-39. Regarding the limitation that the therapeutic composition comprises a porous matrix which comprises a therapeutic and a surfactant, since the composition can is dried by lyphilization it is inherent that there will be pores filled with atmospheric gas within the solid composition. Unger also teaches a broad range of actives that can be used in therapeutic drug delivery including Taxol. See col 22 lin 9-12. Several gases are described within Unger that can be trapped within the liposomes within the therapeutic composition including carbon dioxide, oxygen, fluorine, argon, nitrogen ect. See col 16 lin 8-13. Regarding claims 19 and 20 which are product by process claims "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Claims 1-4,6-9,19-20,28,39-45 are rejected under 35 U.S.C. 102(b) as being anticipated by DeLuca et al. (US 4,818,542).

DeLuca teaches controlled release drug delivery systems comprised of a spherical microporous polymeric network containing pore incorporated drugs, the polymeric network contains polymers selected from PGA, PLA, PGA and PLA copolymer and polyethylene oxide. See abstract and col 3 lin 66-col 4 lin 36. Depending on the application the porous microspheres in DeLuca can be administered alone or in admixture with pharmaceutical diluents, carriers, excipients or adjuncts, for instance for intravenous, intramuscular or subcutaneous administration a suitable sterile aqueous or non-aqueous solution will be employed. See col 6 lin 32-53. Regarding claims 19 and 20 Deluca teaches that the microporous network is formed by forming emulsified droplets of spheres comprising a homogenous mixture of polymer, solvent and active material and removing the solvent by freeze drying or dilution-precipitation extraction. See col 6 lin 6-31. Also claims 19 and 20 are product by process claims therefore the argument above in Unger also applies for DeLuca. Regarding claim 28 DeLuca teaches that the microspheres can have a diameter range of 0.5 to 50 microns within applicants claimed range. Regarding claims 39 and 40 it is considered inherent by the examiner that since the polymer matrix within DeLuca is porous it would at least contain atmospheric gasses such as oxygen, nitrogen and carbon dioxide, therefore the limitations on the type of gas(es) are met.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4,6-10,13-15,19-20,23-25,28 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Unger et al. (US 5,469,854).

Unger is disclosed above.

Regarding the limitation in claim 10 that the additive is PEG-400 it would have been obvious to the skilled artisan that PEG-400 could be selected among the disclosed viscosity modifiers because Unger teaches that the viscosity modifiers such as polyethers should contain a MW between 400 and 8000, therefore PEG-400 is obviously one of the polyethers encompassed within this broad range (polyethylene oxide and PEG are the same polyether). See col 13 lin 25-53.

Claims 1-4,6-10,13-15,19-20,23-25,28 and 39-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLuca et al. (US 4,818,542) in view of Steuart et al. (US 5,330,756) and in view of Unger et al. (US 5,469,854).

Deluca is disclosed above.

While Deluca discloses that the agent used in the invention is specifically encompassed within any diagnostic or pharmaceutically active material, which would be generally classifiable as a drug suitable for introduction into a human, the patent does not specifically mention the exact drug taxol. Deluca also discloses the use of

surfactants and polyethylyene oxide (same as PEG) but is silent on the use of the specific polymer PEG-400.

Steurt discloses the use of therapeutic compositions containing taxol impregnated in porous/fibrous matrixes. See col 3 lin 58-col 4 lin 10 and col 6 lin 23-38. Taxol was disclosed as being useful for treatment of certain cancers.

Ungar discloses that PEG-400 could be selected for use in a therapeutic composition as a viscosity modifier, see above. Viscosity modifiers were disclosed in Unger as capable of stabilizing the porous therapeutics in solution.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Deluca discloses all of applicants claimed invention except for the use of taxol and PEG-400 while from the disclosures of Steurt and Ungar it was already well known in the art to use taxol and PEG-400 in porous matrix therapeutic compositions. The motivation to combine the above documents would be to produce a therapeutic porous matrix that comprised taxol as the active ingredient and PEG-400 as a surfactant. The advantage of such a composition would be to provide parental administration to a subject in need of a treatment requiring taxol, while the use of PEG-400 would stabilize the porous matrix in solution. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D.

whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER